

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY)	
AVERAGE WHOLESALE PRICE)	
LITIGATION)	MDL No. 1456
)	
THIS DOCUMENT RELATES TO:)	Master File No. 01-CV-12257-PBS
)	
STATE OF NEVADA v. AMERICAN HOME)	Judge Patti B. Saris
PRODUCTS CORP., et al., Civil Action No.)	
02-12086-PBS)	

**LOCAL RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS IN
FURTHER SUPPORT OF DEFENDANT ASTRAZENECA PHARMACEUTICALS LP's
MOTION FOR SUMMARY JUDGMENT**

Pursuant to Local Rule 56.1, Defendant AstraZeneca Pharmaceuticals LP
("AstraZeneca") hereby submits its statement of undisputed material facts in further support of
its motion for summary judgment.

1. For AstraZeneca's self-administered drugs ("SADs") covered under the Nevada
Medicaid program, all prescribing decisions are made by physicians. In turn, pharmacists
dispense the drugs, and are subsequently reimbursed by Nevada Medicaid. (Declaration of
Gregory K. Bell, Ph.D., Submitted in Support of Defendants' Motions for Summary Judgment,
filed February 8, 2007 in support of Defendants' Joint Motion for Summary Judgment ("Bell
Decl.") ¶ 7.)

2. Physicians make the decision as to which SAD to prescribe, and the physician does
not pay for and is not reimbursed for the drug. (Bell Decl. ¶ 7.)

3. Pharmacists must dispense the specific branded drug prescribed by a physician.
(Bell Decl. ¶ 7.)

4. Market conditions and the distribution process for AstraZeneca's SADs eliminate any incentive for AstraZeneca to attempt to increase pharmacy margins. (Bell Decl. ¶ 10.)

5. From 1991 to 2004, the top five AstraZeneca SADs (not subject to a Federal Upper Limit ("FUL") through 2004) prescribed and reimbursed for under the Nevada Medicaid program were: (1) Seroquel (quetiapine); (2) Prilosec (omeprazole); (3) Nexium (esomeprazole); (4) Pulmicort Respules (budesonide inhalation suspension); (5) Plendil (felodipine). These five drugs comprised over 80% of the State of Nevada's (the "State") total Medicaid expenditures for AstraZeneca drugs during this period. (Merits Report and Expert Declaration of Joel Winterton in the Nevada AWP Litigation, filed February 8, 2007 ("Winterton Decl.") ¶ 30; Declaration of James J. Duffy in Support of Defendant AstraZeneca Pharmaceutical LP's Individual Memorandum of Law in Further Support of Its Motion for Summary Judgment ("Duffy Decl.") ¶ 2, Ex. 1; Centers for Medicare & Medicaid Services: Medicaid Prescription Reimbursement Information By State, *available at* http://www.cms.hhs.gov/MedicaidDrugRebateProgram/08_MdPresReimInfo.asp; Centers for Medicare & Medicaid Services: State Drug Utilization Data, *available at* <http://www.cms.hhs.gov/MedicaidDrugRebateProgram/SDUD/list.asp>.)

6. For the purposes of his analysis, Dr. Hartman equates pharmacy acquisition cost with Wholesale Acquisition Cost ("WAC"): "I understand that the retail acquisition cost (RAC) is approximately equal to WAC and indeed may be slightly less {that is, $RAC(EAC) < WAC$ }, perhaps 1-2% of AWP. To be conservative, I assume that $RAC = EAC \sim WAC$." (Calculation of Damages and Penalties for the State of Nevada, Declaration of Raymond S. Hartman ("Hartman NV Decl.") ¶ 23, Duffy Decl. ¶ 3, Ex 2.)

7. From 1991 to 2004, the “spread” between Average Wholesale Price (“AWP”) and WAC for all of AstraZeneca’s Medicaid-covered drugs, including the top five SADs, was either 20 or 25 percent. (Winterton Decl. ¶¶ 13, 31 n.15, Duffy Decl. ¶ 2, Ex. 1.)

8. Taking into account Medicaid “Best Price” rebates paid by AstraZeneca, the average net Medicaid reimbursement paid by the State was between 8.5 and 41.4 percent less than what Nevada pharmacies paid to acquire the top five AstraZeneca SADs prescribed and reimbursed for under the Nevada Medicaid program. (Winterton Decl. ¶¶ 17, 23, relying on AstraZeneca pricing data, including Average Manufacturer Price (“AMP”), Best Price (“BP”), and Medicaid Rebate Per Unit data for the years 1991 through 2004, Duffy Decl. ¶ 2, Ex. 1.)

9. Taking into account Medicaid “Best Price” rebates paid by AstraZeneca, the average net Medicaid reimbursement paid by the State for Seroquel was roughly 17 percent less than what Nevada pharmacies paid to acquire this drug. (Winterton Decl. ¶ 23 and Figure 2, relying on AstraZeneca pricing data, including AMP, BP, and Medicaid Rebate Per Unit data for the years 1991 through 2004, Duffy Decl. ¶ 2, Ex. 1.)

10. Nevada pharmacies are not fully compensated for their dispensing costs by the dispensing fees paid by the State’s Medicaid program. (Winterton Decl. ¶¶ 16, 44, Duffy Decl. ¶ 2, Ex. 1; Declaration of Eric M. Gaier, Ph.D., Submitted in Support of Defendants’ Joint Motions for Summary Judgment in Montana and Nevada, filed February 8, 2007 in support of Defendants’ Joint Motion for Summary Judgment (“Gaier Decl.”) ¶¶ 16-29.)

11. The Nevada Medicaid dispensing fee for 2004 was \$4.76 and the average cost to dispense a prescription was \$12.71 in 2006. (Winterton Decl. ¶ 43, Duffy Decl. ¶ 2, Ex. 1; Grant Thornton LLP, National Study to Determine the Cost of Dispensing Prescriptions in

Community Retail Pharmacies, January 2007 (“National Dispensing Cost Study”), Duffy Decl. ¶ 4, Ex. 3.)

12. A 2005 study of pharmacies in 13 states stated that the average cost to dispense a drug was \$9.62. (Winterton Decl. ¶ 43, Duffy Decl. ¶ 2, Ex. 1; The Center for Pharmacoeconomic Studies, The University of Texas at Austin, Summer 2005 (NACDSV01110-12), Duffy Decl. ¶ 5, Ex. 4.)

13. In 2004, Nevada pharmacies incurred a net average loss of roughly 3 percent in dispensing AstraZeneca’s top five drugs under the State’s Medicaid program, when the underpayment of dispensing fees is taken into account. (Winterton Decl. ¶¶ 17, 44 and Figure 17, Duffy Decl. ¶ 2, Ex. 1; National Dispensing Cost Study, Duffy Decl. ¶ 4, Ex. 3; AstraZeneca pricing data, including WACs; Centers for Medicare & Medicaid Services: State Drug Utilization Data, *available at* <http://www.cms.hhs.gov/MedicaidDrugRebateProgram/SDUD/list.asp>.)

14. In 2004, Nevada pharmacies incurred a net average loss of 2 percent in dispensing Seroquel to Medicaid beneficiaries, when taking into account the underpayment of dispensing fees. (Winterton Decl. ¶¶ 17, 44 and Figure 17, Duffy Decl. ¶ 2, Ex. 1; National Dispensing Cost Study, Duffy Decl. ¶ 4, Ex. 3; AstraZeneca pricing data, including WACs; Centers for Medicare & Medicaid Services: State Drug Utilization Data, *available at* <http://www.cms.hhs.gov/MedicaidDrugRebateProgram/SDUD/list.asp>.)

15. Nevada hospitals, universities, prisons, and other State non-Medicaid entities purchased significant volumes of AstraZeneca products at prices below the Medicaid reimbursement rate for ingredient cost. (Gaier Decl. ¶¶ 30-34.)

16. The idea that pharmaceutical manufacturers would purposefully create a “spread” between AWP and the acquisition costs of their branded outpatient drugs makes no sense. (Bell Decl. ¶ 10.)

17. Dr. Hartman concluded that payers were aware that AWPs are greater than ASPs, but as an important publicly available price, they rely on AWPs to bear a predictable relationship to ASPs. (Declaration of Raymond S. Hartman in Support of Plaintiffs’ Claims of Liability and Calculation of Damages, dated December 15, 2005 (“Hartman MDL Decl.”) ¶ 33, Duffy Decl. ¶ 6, Ex. 5.)

18. Dr. Hartman calculated this reasonable expectation to be a 30 percent spread between AWP and ASP, which he has described as a liability threshold.

Q: Are you willing to stand by your December 15 report as a reasonable determination of liability and damages in this case?

A: I stand by my report that should the Court come to the decision that the -- that a finding of liability is related to the expectation, the pricing expectations in the market, then I would -- I would stand by this report of a threshold, of a liability threshold of 30 percent.

(Deposition of Raymond S. Hartman, dated February 22, 2006 (“Hartman I Dep.”), at 665, Duffy Decl. ¶ 7, Ex. 6.)

19. Dr. Hartman’s yardstick theory applies to both third-party payers, on whose behalf the State asserts claims, and to state Medicaid agencies, who are market participants.

Q: And the yardstick that you used was 30 percent, correct?

A: That's correct.

...

Q: And that expectation would apply to the Medicaid agencies as well as the rest of the marketplace, is that correct?

A: This expectation and this understanding was a -- a general statement for the market as a whole.

Q: And that would include Medicaid, correct?

A: It -- it includes all market participants.

Q: Including Medicaid, correct?

A: That's right.

(Deposition of Raymond S. Hartman, dated August 22, 2006 ("Hartman II Dep."), at 32, Duffy Decl. ¶ 8, Ex. 7.)

20. The basis of Dr. Hartman's liability opinion is that Defendants' alleged misconduct caused Nevada to reimburse pharmacies at levels above their acquisition costs for Medicaid-covered drugs. (Calculation of Damages and Penalties for the State of Nevada, Declaration of Raymond S. Hartman ("Hartman NV Decl.") ¶ 3, Duffy Decl. ¶ 3, Ex 2.)

21. In Dr. Hartman's "but-for" world, the State should have been reimbursing pharmacies at the exact dollar amount paid by the pharmacies to acquire the relevant Medicaid-covered drugs. (Hartman NV Decl. ¶ 16(1b), Duffy Decl. ¶ 3, Ex 2.)

22. In Dr. Hartman's "but for" world, Nevada pharmacies in 2004 would have incurred a significant loss every time they dispensed one of the top five AstraZeneca Medicaid-covered drugs, and a net loss of 3.6 percent in dispensing AstraZeneca's top products. (Winterton Decl. ¶ 44 and Figure 17, Duffy Decl. ¶ 2, Ex. 1; National Dispensing Cost Study, Duffy Decl. ¶ 4, Ex. 3; AstraZeneca pricing data, including WACs; Centers for Medicare & Medicaid Services: State

Drug Utilization Data, *available at*

<http://www.cms.hhs.gov/MedicaidDrugRebateProgram/SDUD/list.asp>.)

23. In his Declaration, Dr. Hartman states that he does not calculate damages for the State's claims related to purported payments by the Nevada Medicaid program to cover the 20 percent Medicare Part B co-payments made on behalf of individuals who are dually-eligible for Medicare and Medicaid benefits because he did not receive sufficient data from the state to make this calculation. (Hartman NV Decl. ¶ 30, Duffy Decl. ¶ 3, Ex. 2.)

24. The State has produced no data relating to physician-administered drugs and, therefore, Dr. Hartman does not attempt to calculate damages for these drugs. (Hartman NV Decl. ¶¶ 16 n. 22, 23(c), 30, Duffy Decl. ¶ 3, Ex. 2.)

25. The State has produced no claims data for claims after 2002 and, therefore, Dr. Hartman does not attempt to calculate damages or penalties for these claims. (Hartman NV Decl. ¶ 16 n. 22, Duffy Decl. ¶ 3, Ex. 2.)

26. In his Declaration, Dr. Hartman does not calculate damages for the State's claims related to the losses purportedly suffered by unnamed third-party payers. (Hartman NV Decl. ¶¶ 16 n.22, 32, Duffy Decl. ¶ 3, Ex. 2.)

27. A reduction in Nevada Medicaid reimbursement rates would have caused pharmacies to close, threatening access to care for rural Nevadans.

Q: This is--I believe this is your testimony.

A: Okay.

Q: There is a considerable problem in our state, problems of health care in our state. This does not only address our

pharmacies, it addresses pharmacies, the retail pharmacies within hospitals. It addresses rural health care. It's easy to assume a hospital in Las Vegas can absorb the cost of [a reduction in the Medicaid reimbursement rate], but can you assume that an Ard Olson can absorb the cost of this within Ely Nevada. A large percentage of his patients, a large percentage of his customers have to depend on having rural health care, and I would be preaching to the choir if I did not tell you. Rural health care is in a very, very bad mess in Nevada.

A: Uh-huh. See, I haven't changed my opinion.

Q: So you recall this particular testimony then?

A: Yes, now that you pointed it out to me.

(Deposition of Mary Lau, dated March 13, 2006, at 24, Duffy Decl. ¶ 9, Ex. 8.)

28. In order to determine the net reimbursement paid to a retail pharmacy for dispensing a Medicaid prescription, the sum of the ingredient cost reimbursement level and the dispensing fee must be taken into account. (Winterton Decl. ¶ 43, Duffy Decl. ¶ 2, Ex. 1.)

I swear under penalty of perjury under the laws of the State of New York and the United States of America that the foregoing is true and correct.

Dated: Boston, Massachusetts
February 8, 2007

Respectfully Submitted,

By: /s/ Katherine B. Schmeckpeper

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CERTIFICATE OF SERVICE

I hereby certify that on February 8, 2007, I caused a true and correct copy of the foregoing, Declaration of James J. Duffy in Support of the Individual Memorandum of Law in Further Support of AstraZeneca Pharmaceuticals LP's Motion for Summary Judgment, to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 in MDL No. 1456.

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